

REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 11-19 and 21-29) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides a radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment that is useful in the practice of nuclear medicine, in which a radioactive dose is able to be provided in a plunger-operated syringe, in an automated fashion, thereby obviating the need for any person to physically handle any radioactive material. As now practiced in the art, dose fractionation of required radioactive solutions is largely a manual process performed by a medical technician behind a lead-shielded screen for minimizing exposure to radiation. This manual procedure is rather time-consuming, as the medical technician is required to successively withdraw iterations – small volumes of the radioactive tracer – until the targeted dose amount is reached. The presently claimed invention provides overcomes the drawbacks of the manual procedure known to the prior art by providing accurate means for automatically dispensing individual doses of a radioactive solution into vials, or syringes, under aseptically-controlled conditions, while minimizing the exposure of radiation to a medical technician, or other operator, which would otherwise be associated with the manual manipulation of radioactive solutions.

As now most broadly claimed, the present invention provides a radioactive dose

dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which includes a container formed as a plunger-operated syringe and means for radiation shielding of the radioactive dose dispensing apparatus. Further, means are provided for controlling a mix of radioactive stock solution and dilution stock solution, as well as means for detecting radioactivity of the mix of the radioactive stock solution and the dilution stock solution. In a departure from the prior art, the means for controlling a mix of radioactive stock solution and dilution stock solution results in automatically diluting the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into the container; the prior art teaching the separate step of diluting a radioactive isotope in a dilution vial, rather than via controlling the mix of the radioactive stock solution and the dilution stock solution.

Further, in an alternative, preferred embodiment of the present invention, which is neither taught nor suggested by the prior art, a programmable logic controller is included for automating the radioactive dose dispensing apparatus and for calculating a required dosage. The programmable logic controller ("PLC") is operable in combination with a radiation detector for controlling the radioactive dose being dispensed into the plunger-operated syringe, in contrast to that taught and suggested by the prior art.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and efficient radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which automatically

dilutes the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into the container, either disclosed or suggested.

By the present amendments, Applicants have amended independent Claim 11 (and Claims 12-19 via dependency) to now recite that the means for controlling a mix of radioactive stock solution and dilution stock solution operate to “automatically dilut[e] the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into said container,” as explained in Applicants’ *Specification* at Page 6, lines 5-19, and as understood with reference to drawing FIGS. 1-3.

Dependent Claims 12-16 have been amended to delete the term “disposable,” in reference to the operated-plunger syringe, so that it is understood that the operated-plunger syringe need not be “disposable.” New dependent Claim 21 has been added to recite the use of a “disposable” syringe as a preferred embodiment.

Dependent Claim 19 has been amended to attend to the correction of a typographical error noted by the Examiner, while independent Claim 20 has been canceled as being directed to the non-elected invention following Applicants’ election in response to the Examiner’s restriction requirement of the first Office Action.

Applicants have also taken this opportunity to add new Claims 22-29. Newly-entered independent Claim 22 recites the use of a programmable logic controller (“PLC”)

for automating said radioactive dose dispensing apparatus and calculating a required dose, and further recites the preferred use of a “plunger-operated syringe” as the “container” used in practicing of the present invention. New dependent Claims 23-29 track the subject matter of various claims that are dependent upon independent Claim 11.

Turning now, in detail, to an analysis of the Examiner’s prior art rejections, initially, in the second Office Action the Examiner has rejected independent Claim 11 as being anticipated, pursuant to 35 U.S.C. §102(b), by Matsuno *et al.*, U.S. Patent No. 5,039,863. By broadly applying the prior art of Matsuno *et al.* against the “means-plus-function” elements of Claim 11, the Examiner has taken the position that the applied citation discloses an “equivalent” to the each of the means for practicing the claimed invention as recited in Claim 11, as examined prior to the newly-entered amendments.

In reply to the Examiner’s anticipation rejection applying Matsuno *et al.*, the applied reference teaches the inclusion of a “dilution vial so that the RI solution and the physiological saline solution are transferred to the dilution vial to prepare a diluted RI solution.” (Matsuno *et al.* at Col. 3, lines 10-14) Applicants’ presently claimed invention, in sharp contrast to that which is disclosed and suggested by Matsuno *et al.*, now recites in independent Claim 11 that the means for controlling a mix of radioactive stock solution and dilution stock solution operate to “automatically dilut[e] the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into said container,” thereby obviating the separate, and less efficient, need for a separate mixing in a dilution vial.

Because Matsuno *et al.* teaches use of a dilution vial, rather than means for a controlled mixing which accomplishes the intended dilution upon the radioactive stock solution and the dilution stock solution passing into the plunger-operated syringe, or other type of container, it cannot reasonably be seen that Matsuno *et al.* either anticipates, or renders obvious, the present invention as now recited in independent Claim 11 (or Claims 12-19 and 21, which either directly or indirectly depend from Claim 11.)

Accordingly, withdrawal of the Examiner's 35 U.S.C. §102(b) anticipation rejection of the second Office Action, which applies Matsuno *et al.*, is respectfully requested.

Separately, as part of the second Office Action, the Examiner has rejected the subject matter of dependent Claim 16, which is now substantially the same as new independent Claim 22, as being obvious, pursuant to 35 U.S.C. §103(a), over Matsuno *et al.* on the contention that the cited reference discloses a programmable logic controller, as designated by numeral "14" in Matsuno *et al.* with reference being made to Col. 8, lines 59-60, thereof. (While the obviousness rejection of dependent Claim 16 is a part of ¶ 9 of the Action, it does not appear that the Examiner has secondarily-applied Cassel, U.S. Patent No. 5,911,252, in rejecting the subject matter of Claim 16.)

In reply to the Examiner's obviousness rejection of the subject matter of dependent Claim 16, as now applicable to new independent Claim 22, Matsuno *et al.* describes the use of a "computer 14," rather than a programmable logic controller ("PLC"), as is utilized in Applicants' invention, which differs from a "general purpose" computer in

significant ways. More particularly, *Wikipedia, The Free Encyclopedia* describes the specialized nature of a programmable logic controller, as follows:

A **programmable logic controller (PLC)** or **programmable controller** is a digital computer used for automation of electromechanical processes, such as control of machinery on factory assembly lines, control of amusement rides, or control of lighting fixtures. PLCs are used in many different industries and machines such as packaging and semiconductor machines. Unlike general-purpose computers, the PLC is designed for multiple inputs and output arrangements, extended temperature ranges, immunity to electrical noise, and resistance to vibration and impact. Programs to control machine operation are typically stored in battery-backed or non-volatile memory. A PLC is an example of a real time system since output results must be produced in response to input conditions within a bounded time, otherwise unintended operation will result. (emphasis added)

See, http://en.wikipedia.org/wiki/Programmable_logic_controller

Inasmuch as Matsuno *et al.* fails to teach the use of a “programmable logic controller,” as recited in newly-entered independent Claim 22, which cannot be properly be seen as the equivalent of “general-purpose computers,” it cannot be properly said that Matsuno *et al.* renders obvious that which is now recited in new Claims 22-29.

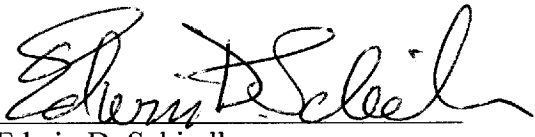
In view of the foregoing, it is respectfully contended that the subject matter of newly-presented independent Claim 22 is not obvious over the prior art, as applicable and applied against dependent Claim 16.

Concerning, finally, the remaining references cited by the Examiner, but not applied in any rejection of Applicants’ claims, such additional references have been carefully considered, but are not deemed to adversely affect the patentability of the present invention, as now claimed.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 11-19 and 21-29) recite a novel and efficient radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which automatically dilutes the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into the container, which is patentably distinguishable over the prior art. Accordingly, withdrawal of the outstanding rejections and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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Enc.: 1. Petition for Three-Month Extension of Time for Response; and,
2. EFT for \$555.00 (Three-Month Extension Fee).

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (*Account No. 19-0450*) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.